

GROWERS AND PACKERS OF
FRESH AND FROZEN SEAFOOD

DOCKETS MANAGEMENT BRANCH (HFA-305)

Food and Drugs Administration

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

March 25, 1999

7400 '99 APR -2 A9:42

Sub: Docket No. 98P-0504; Performance Standards for Vibrio Vulnificus

Our comments on the issue petitioned by the Center for Science in the Public Interest, in sequence of questions posed are:

- 1) Technologies cannot be applied, or mandated, across the board to all types of shellfish and processes used in their manufacturing. Barriers to the use of a single technology are based on differences in process and products. End use of a product should determine the processes that need to be applied to ensure food safety;
- 2) Other technologies such as pulsed light and high-pressure application are being experimented with and may have a better resolution, based on end use of product;
- 3) Technology cannot be mandated for any industry and would be a violation of the principles of freedom and choice. One size does not fit all. There are enough restrictions and regulations already in place. Performance standards, if reasonable, may be mandated;
- 4) Zero tolerance does not work and there is no scientific basis for it. The winter month's MPN level is a good starting point for work towards a performance standard. Consideration should be given to the minimum infectious dose;
- 5) The application of a performance standard is relevant to areas of concern and areas identified as being a problem. It is not a good policy to apply standards where they are not necessary or incidences are not on record. The significant issue involves consumption of raw shellfish, and should not be applied in cases where further processing is a factor;
- 6) The costs of meeting and testing to a performance standard should be fairly high and will cause damage to the industry. Invariably these costs are borne by the processor and then indirectly passed on to the consumers;
- 7) The only persons to benefit from these standards would be immune-compromised individuals, specifically people with liver disease. These individuals should stay away from eating raw food products and the population at large are best served by education of these individuals;
- 8) No comment on this point;

The CSPI has the narrow interest of a small cross section of the American population. The public they seek to serve will cost the rest of the population their freedom of choice in matters of food selection and consumption. Food safety issues based on the most vulnerable population will do great injustice to the majority of Americans. Commercial sterility will need to be guaranteed for all food that may be consumed by this population and this goal is neither desirable nor should it be entertained. The great variety of food in this country exists because the consumers want, rather demand, this diversity of form, state of process, and function. Their freedom of choice is not secondary to the demands of groups like the CSPI.

Education is the key to a harmonious solution. Education is essential for the entire community of at risk population, about safe choices they may make in the foods they consume. The CSPI will be doing their duty if they spend time on this and seek to serve both **Science** and the **Public**.

Sincerely,

J. Mukerji
Manager QA

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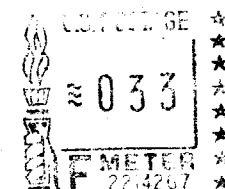
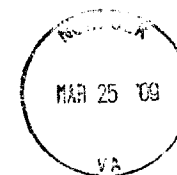


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